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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,578	02/06/2004	Jose A. O'Daly	299 P 099	6726

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EXAMINER

AFREMOVA, VERA

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/773,578

Applicant(s)

O'DALY, JOSE A.

Examiner

Vera Afremova

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of the Group II, claims 5-8, in the reply filed on 8/08/2005 is acknowledged.

Claims 1-4 have withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 5-8 are under examination in the instant office action.

Claim Objections

Claims 6-8 are objected to because of the following informalities:

Claim 6 is missing indication of its dependency on claim 5.

Claims 6 and 8 contain some typing error in chemical names, in abbreviated names and in the use of parenthesis. For example: see claimed phrase "panthotenato" (claim 6, line 10 and claim 7, line 10) and also see 2 abbreviations starting with "(d-...." (claim 6, line 5 and claim 7, line 5).

Latin names of organisms should be italicized (claim 7).

Appropriate corrections are required.

Claim Rejections - 35 USC § 112

Claims 6 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 8 are indefinite with regard to the culture medium ingredients as required for culturing parasitic organism. It is unclear what is "panthotenato" as presently claimed. In the

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instant office action it is believed to mean “pantothenic acid”. The phrase “(d, 2'-deoxyuridine-5-monophosphate (d, 2'-deoxyguanilic Acid (d-GMP))” is mistyped and its meaning is uncertain.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,458,581 (Lemerse).

Claims are directed to a method of maintaining a parasitic organism *in vitro* wherein the method comprises one active step of contacting a culture containing a parasitic organism with a serum-free culture medium. Some claims are further drawn to the parasitic organism being a member of the *Leishmania* genus in the amastigote stage.

US 6,458,581 (Lemerse) teaches a method of maintaining a parasitic organism *in vitro* by culturing the parasitic organism culture in a serum-free culture medium (see entire document including abstract; col. 3, lines 3-64; col. 18, lines 19-22). The parasitic organisms include members of the *Leishmania* genus in the amastigote stage (col. 18, lines 10-22).

Thus, the cited patent US 6,458,581 (Lemerse) clearly anticipates presently claimed invention.

Claims 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Daly et al. (“Differential growth requirements of several *Leishmania* sp. in chemically defined culture media”. Acta Tropica (1988), 45: 109-126).

Claims are directed to a method of maintaining a parasitic organism *in vitro* wherein the method comprises one active step of contacting a culture containing a parasitic organism with a serum-free culture medium. Some claims are further drawn to the use of chemically defined culture medium comprising particular list of specific ingredients.

The reference by O'Daly et al. teaches a method of maintaining parasitic organisms including members of the *Leishmania* genus in an *in vitro* culture system by culturing or contacting the parasitic organisms with a serum-free culture medium (see entire document including page 110, last par., especially line 7 and Fig. 1). The culture medium "ESM" comprises particular ingredients identical to the presently claimed ingredients (pages 120-124, tables 1a, 1b and 2).

Thus, the cited reference clearly anticipates presently claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,458,581 (Lemerse) and O'Daly et al. ["Differential growth requirements of several *Leishmania sp.* in chemically defined culture media". *Acta Tropica* (1988), 45: 109-126] taken with GIBCO catalogue and patents US 4,687,666 (O'Daly) and US 6,673,351 (O'Daly).

Claims are directed to a method of maintaining a parasitic organism *in vitro* wherein the method comprises one active step of contacting a culture containing a parasitic organism with a

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serum-free culture medium. Some claims are further drawn to the parasitic organism being a member of the *Leishmania* genus in the amastigote stage. Some claims are further drawn to the use of chemically defined serum-free culture medium comprising particular list of specific ingredients. Some claims are further drawn to culturing representatives of the *Leishmania* genus in the amastigote stage in the chemically defined serum-free culture medium comprising particular list of specific ingredients.

The cited US 6,458,581 (Lemerse) and O'Daly et al. are relied upon as explained above.

The culture medium in the method of the cited US 6,458,581 (Lemerse) comprises major groups of nutrients required for culturing parasitic organisms in the amastigote stage and in the promastigote stage including components of medium 199 supplemented with additional nutrients such as glucose, glutamine, salts, various vitamins, anti-oxidizing agent hemin, buffer HEPES, etc. The components of prior art medium 199 are disclosed in GIBCO catalogue (pages 91-92) and they comprise other additional components including precursors of nucleic acids and additional vitamins. Thus, even if the medium in the method of the cited US 6,458,581 (Lemerse) might be different with regard to same minor components, for example: particular precursors of nucleic acids, vitamins and/or thiotic acid, it clearly provides for continuous growth of parasitic organisms including members of the *Leishmania* genus in the amastigote stage in a serum-free environment. US 6,458,581 (Lemerse) teaches that absence of serum advantageously produces an inexpensive product (col. 4, line 46).

The serum-free chemically defined culture medium that is used in the method of the cited reference by O'Daly et al. is identical to the serum-free culture medium in the presently claimed method (tables 1a, 1b and 2). The fact that the medium components are identical is also

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supported by the disclosure in the O'Daly's patents US 4,687,666 (table 1) and US 6,673,351 (table 1). But the medium is supplemented with serum as disclosed in US 4,687,666 and as disclosed for preferred embodiment in US 6,673,351. However, the method in the cited reference by O'Daly et al. discloses culturing members of the *Leishmania* genus in the same medium but free of serum (fig. 1). Although it is not particularly clear as disclosed what is a developmental stage of *Leishmania* organisms cultured in the serum free medium, the cited reference recites that parasitic organisms were isolated from infected mammals (see "infected hamsters" at page 110, last par.). Thus, there is a reasonable believe that parasites were in the amastigote stage when isolated and contacted/cultured with the synthetic chemically defined serum-free medium, because US 6,458,581 (Lemerse) teaches that *Leishmania* organisms are present in the amastigote stage in a mammalian host (col. 1, lines 45-48). The cited US 6,673,351 also suggests that in order to obtain first-generation immunotherapeutic agent *Leishmania* organisms can be cultured in synthetic and serum-free medium (col.7, lines 24-27).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use serum-free medium disclosed by the reference by O'Daly et al. and in patents US 4,687,666 (O'Daly) and US 6,673,351 (O'Daly) with a reasonable expectation of success in culturing parasitic organisms including members of the *Leishmania* genus in the amastigote stage because the parasitic organisms including members of the *Leishmania* genus can be cultured in a defined serum-free medium as taught by US 6,458,581 (Lemerse). One of skill in the art would have been motivated to use a serum-free medium for the expected and advantageous benefits in producing inexpensive products as taught by US 6,458,581 (Lemerse).

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Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

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October 13, 2005



VERA AFREMOVA

PRIMARY EXAMINER